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Dockets Management Branch,
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HGA-305)
Rockville, Maryland 20852

RE: Docket Number 02D-0039:

Comments to Proposed Guidance, "Premarket Notification [510(k)] Submissions for Medical Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA"

DePuy Orthopaedics, Inc., A Johnson & Johnson Company, submits in duplicate the following comments in response to the proposed FDA Guidance:

Text (page 1, 2nd paragraph):

"A person intending to market a sterilization packaging system intended for the terminal sterilization of medical devices in health care facilities must submit to FDA, and have cleared, a premarket notification submission prior to introduction of the product into interstate commerce..."

Comment:

It is not clear from this statement that the responsibility for the sterilization packaging system 510(k) should be submitted by the actual manufacturer (e.g., Symmetry/Polyvac) who sells a sterilization packaging system to the designing/marketing company, or by the design/marketing company (e.g., DePuy), or both.

Text (page 2, 1st paragraph):

"This guidance includes sterilization trays and cassettes...because they are intended to enclose medical systems for terminal sterilization and they are considered a medical sterilization packaging system. Therefore they are Class II devices requiring the submission of a premarket notification [510(k)]."

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Comment:

DePuy does not agree with the designation of sterilization cassettes as Class II devices, since 21 CFR 880.5850, Sterilization Wrap, reads "...and also to maintain sterility of the enclosed device until used". This guidance correctly makes this important distinction in its definition of a sterilization cassette (page 3, C., Definitions) where it states that *"To maintain sterility, they are enclosed in a sterilization wrap"*. Further, on page 17, this guidance states, "*The cassette itself cannot maintain sterility. No claims can be made* for maintenance *of sterility unless the cassette is wrapped with sterilization wrap".* DePuy agrees that sterilization cassettes are an accessory (page 3, paragraph one), but are still class I devices. The sterilization wrap, which is not typically supplied by the company supplying the tray/cassette and is applied by the hospital facility doing the sterilization, is the class II device.

It is suggested that the requirements for *sterilization cassettes* be segregated from those of *Rigid Sterilization Containers*, to alleviate the potential confusion between the two systems. It is also recommended that pictures be incorporated into the guidance to facilitate understanding of the different types of systems.

Text (page 10, first bullet):

"You should submit performance data comparing the characteristics of sterilant penetration of your device with the predicate. Your device should be porous enough to allow adequate sterilant penetration or conductance"

Comment:

Performance data for a sterilization cassette can only be determined by the use of thermocouple wires, as sterility would be compromised after sterilization. It was previously acknowledged in this guidance that sterilization cassettes, as an accessory, do not maintain sterility without the benefit of another device (wrap). It is suggested that additional clarification be provided regarding the limitations of the test methods available.

Text (page 10, second bullet):

"You should submit performance data comparing the packaging integrity properties of your device with the predicate. To maintain sterility, your device should be impermeable to microorganisms."

Comment:

It is acknowledged in this guidance that sterilization cassettes, as an accessory, do not maintain sterility without the benefit of another device: (reference, page 3, definition, *"To maintain sterility, they are enclosed in a sterilization wrap"*, and page 11, last paragraph, *"Sterilization cassettes and trays require sterilization wrap").* Again, as noted above, the sterilization tray or cassette, does not maintain sterility; the sterilization wrap used by the hospital facility is a separate device that is responsible for the maintenance of sterility.

Text (page 11, 2):

"Cassettes"

It does not seem appropriate to list sterilization wrap as a design requirement for a cassette, given the number of manufacturers in existence.

Text (page 11, 6):

"Limits of reuse"

Comment:

The manufacturer cannot accurately predict the limits of reuse for a sterilization cassette, as "normal" use can vary significantly between end-users. For example, some hospitals purchase and maintain sterilization cassettes within their facility, while others contract with third-party reprocessors, who transport them out of state for cleaning and disinfection. It is suggested this requirement be restated to say, "Limitations for reuse", as these should be identified through risk analysis/FMEA studies.

Text (page 14, B):

"Package Integrity"

Comment:

The discussion on Package Integrity is greatly appreciated by industry in that the Agency highlights the differences and limitations between microbial challenge tests and physical tests for microbial barrier properties of packaging systems. We also understand the desire to perform whole package integrity test methods to confirm sterile package integrity. However, there currently are limited test methods to perform such evaluations. Porous materials such as paper and Tyvek severely restrict test methodology. Test apparatus for ASTM D3078 *Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission* is limited to small package sizes only.

It is suggested that the Agency take a similar position as that of ISO 11607-1997, *Packaging for terminally sterilized medical devices,* which is a recognized consensus standard. ISO 11607 established package integrity and sterility maintenance by demonstrating the seal is impermeable and continuous by using physical tests together with microbial barrier property testing of the packaging materials themselves. Possible wording may read:

> While whole package integrity testing is preferred, packaging materials, package size, test methodology and test apparatus can limit the ability to perform such a test. When whole package integrity tests are not possible, it shall be sufficient to demonstrate sterile package integrity by demonstrating that the seal is impermeable and continuous using seal integrity tests and by testing the microbial barrier properties of the material.

This would provide alternatives until appropriate whole package test methods can be developed and standardized.

Text (page 15, 2):

"Microbial Barrier Properties"

Comment:

Performance data for a sterilization cassette cannot be determined as sterility would be compromised after sterilization. It was previously acknowledged in this guidance that sterilization cassettes, as an accessory, do not maintain sterility without the benefit of another device (wrap).

Text (page 17, 5):

"Sterilization Cassette Integrity: The data should show that the enclosed devices are sterile. The cassette itself cannot maintain sterility. No claims can be made for maintenance of sterility unless the cassette is wrapped with sterilization wrap"

Comment:

DePuy agrees that the sterilization cassette as marketed will not maintain sterility. This is why we believe it is does not meet the requirements under 880.6850 as a class II device. Sterility can only be assured with the use of a cleared sterilization wrap, which as stated above, are typically separate devices not provided with or as part of the sterilization tray/cassette and are selected and applied by the hospital facility, not the manufacturer/distributor of the cassette.

Text (page 19, E):

"You should provide...method for tracking the device in the labeling. (Please note that tracking refers only to the facility's tracking system...)"

Comment:

Manufacturers are unaware of the different types of tracking systems in use at hospitals and third-party reprocessors. Consequently, this requirement for labeling/tracking is beyond the control of the tray/cassette manufacturer.

Manufacturers already label/etch a product part and lot number directly onto the sterilization cassette, as required by 21 CFR, Part 820. Some companies, such as DePuy, also apply a HIBCC bar code onto the product label.

Text (page 20, G):

"Biocompatibility"

Comment:

The polymeric tests listed in this guidance, (e.g., Primary Dermal Irritation, Dermal Sensitization, and Blood Hemolysis) are not consistent with the requirements listed in AAMI/ISO 10993-1 with respect to intended user or patient exposure.

Text (page 21, 9th bullet):

"A statement that complex instruments…should be prepared and sterilized according to the instrument manufacturer's instructions."

Comment:

This is inconsistent with the rest of this guidance document, which states that the purpose of this guidance is to assure sterilant penetration for the sterilization packaging system and the devices contained within, i.e., (page 13, A), *"You should provide performance information demonstrating that the sterilant is able to penetrate the sterilization wrap…and sustain direct contact with the medical instruments inside the package…".*

Text (page 22, Sterilization Cassettes):

Comment:

The first and fourth bullets are essentially redundant.

Text (page 23):

"Material composition, physical and chemical properties"

Comment:

It is not clear what is envisioned by the agency for "chemical properties", as it is not described or discussed anywhere else in this document.

Respectively submitted,

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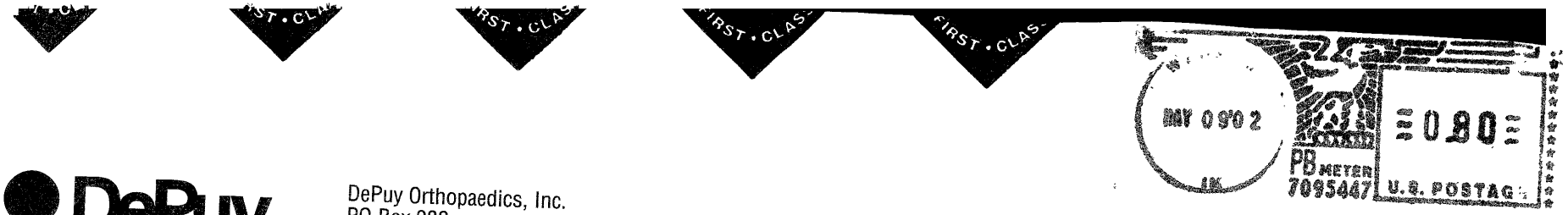
A Johnson & Johnson Company



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